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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,263	09/16/2003	Thomas L. Cantor	532212002000	3408
25225	7590	06/30/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			VENCI, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/664,263	CANTOR, THOMAS L.
	Examiner	Art Unit
	David J. Venci	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on March 31, 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,34,37 and 41-64 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-33,35,36 and 38-40 is/are rejected.
- 7) Claim(s) 32 and 33 is/are objected to.
- 8) Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on September 16, 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/26/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, drawn to a method of "deciding" in view of a "therapeutic inactivating capacity", classified in class 435/7.4, for example.
- II. Claims 27-40, drawn to a method of "deciding" in view of an "assessed auto antibody", classified in class 436/506, for example. [elected]
- III. Claims 41-50, drawn to a method of "deciding" in view of a "chemical moiety-based therapeutic agent", classified in class 424/9.2, for example.
- IV. Claims 51-55, drawn to a kit comprising a "means for assessing therapeutic inactivating component", classified in all of class 600, for example.
- V. Claims 56-57, drawn to a kit comprising a "therapeutic agent", classified in all of class 514, for example.
- VI. Claims 58-64, drawn to a method of "deciding" in view of a "hormone", classified in class 424/158.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and VI are related processes. Related processes are distinct from each other if the inventions, as claimed, are not: (1) overlapping in scope, i.e., are mutually exclusive; (2) obvious variants; and (3) capable of use together or have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

With respect to (1), *supra*, the inventive feature of Inventions I, II, III and VI is the step of "deciding". However, the scope of Inventions I, II and III does not overlap because the step of "deciding" is performed differently in each Invention. For example, Inventions I requires a step of "deciding" in the context of a

Art Unit: 1641

"therapeutic inactivating capacity", while Invention II requires a step of "deciding" in the context of an "assessed auto antibody", while Invention III requires a step of "deciding" in the context of a "chemical moiety-based therapeutic agent", while Invention VI requires a step of "deciding" in the context of a "hormone".

With respect to (2), *supra*, Inventions I, II, III and VI are not obvious variants because said step of "deciding" in Inventions I, II, III and VI have different input parameters and logic structures.

With respect to (3), *supra*, Inventions I, II, III and VI have different modes of operation because Invention I requires, *inter alia*, assessing "therapeutic inactivating capacity", while Invention II requires, *inter alia*, assessing an "auto antibody", while Invention III requires, *inter alia*, assessing a "therapeutic protocol", while Invention VI requires, *inter alia*, assessing "hormone inactivating component".

With respect to Inventions I, II, III and VI, examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the step of "deciding" in the context of a "therapeutic inactivating capacity" of Invention I requires a search of prior art related to livers, while a search for the step of "deciding" in the context of an "assessed auto antibody" of Invention II requires a search of prior art related to immunity, while a search for the step of "deciding" in the context of a "chemical moiety-based therapeutic agent" of Invention III requires a search of prior art related to pharmacokinetics, while a search for the step of "deciding" in the context of a "hormone" of Invention VI requires a search of prior art related to the endocrinology.

Inventions IV and V are unrelated. Inventions are unrelated if the inventions are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs because Invention IV requires

Art Unit: 1641

a "means for assessing therapeutic inactivating capacity", while Invention V requires a "therapeutic agent".

Inventions (I, II, III or VI) and (IV or V) are related as processes of using products. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Inventions IV and V can be used in materially different processes, such as a diagnostic method or treatment method.

This application contains claims directed to the following patentably distinct species:

1. Select ONE therapeutic/medical condition from:
 - a. Pain management; (claims 5 and 6)
 - b. Antipyretic; (claim 5)
 - c. Migraine; (claims 5 and 6)
 - d. Prophylaxis; (claim 5)
 - e. Anti-infective/infection; (claims 5 and 6)
 - f. Anti-inflammatory/inflammation; (claims 5 and 6)
 - g. Anti-parasitic;
 - h. Uterine;
 - i. Anti-microbial;
 - j. Anti-arthritis/arthritis related condition; (claims 5 and 6)
 - k. Gout; (claim 5)
 - l. Cardiovascular; (claims 5 and 6)
 - m. Cancer; (claims 5 and 6)
 - n. Immunomodulation; (claim 5)
 - o. Metabolic; (claims 5 and 6)
 - p. Musculoskeletal; (claims 5 and 6)
 - q. Anti-toxicity; (claim 5)
 - r. Dermatologic; (claims 5 and 6)
 - s. Ophthalmic; (claims 5 and 6)

Art Unit: 1641

- t. Otic; (claims 5 and 6)
- u. Pharyngeal; (claims 5 and 6)
- v. Nasal; (claims 5 and 6)
- w. HIV/AIDS; (claims 5 and 6)
- x. Allergy/asthma; (claims 5 and 6)
- y. Alzheimer's; (claims 5 and 6)
- z. Diabetes; (claims 5 and 6)
- aa. Glandular disorder; (claims 5 and 6)
- bb. Kidney disease; (claims 5 and 6)
- cc. Liver disease; (claims 5 and 6)
- dd. Mental health; (claims 5 and 6)
- ee. Osteoporosis; (claims 5 and 6)
- ff. Parkinson's; (claims 5 and 6)
- gg. Renal bone disease; (claims 5 and 6)
- hh. Parathyroid gland disorders; (claim 5)
- ii. STD; (claims 5 and 6)
- jj. Stroke; (claims 5 and 6)
- kk. Blood/circulatory; (claims 5 and 6)
- ll. Endocrine; (claims 5 and 6)
- mm. Gastrointestinal; (claims 5 and 6)
- nn. Neurological; (claims 5 and 6)
- oo. Respiratory; (claims 5 and 6)
- pp. Urinary; (claim 6)
- qq. OB/GYN; (claim 6)
- rr. Foot related condition; (claim 6)
- ss. Immunological related condition; (claim 6)
- tt. Toxicity related condition; (claim 6)
- uu. Child specific condition; (claim 6)
- vv. Small molecule; (claims 14 and 42) OR
- ww. Biomolecule. (claim 14)

2. Select ONE drug from:

- a. ONE "therapeutic agent" selected from Table 2; (claims 4, 29 and 53)
- b. Erythropoietin/erythropoietin analog; (claims 15, 24, 38, 59 and 62)
- c. Atorvastatin (claim 21);
- d. Epoetin alpha (claim 21);
- e. Paricalcitol (claim 21);
- f. Risperidone (claim 21);
- g. Calcimemetic (claim 21);
- h. Furosemide (claim 21);
- i. Bisphosphonate (claim 21);
- j. Teriparatide (claim 21); OR
- k. Parathyroid hormone (claim 34).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27, 51 and 58 are generic.

Art Unit: 1641

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species are independent or distinct because each specie member does not have a common property, activity, and do not share a common structural feature, i.e., a significant structural element is not shared by all of the alternatives.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

During a telephone conversation with Agent Mike Smith on June 8, 2006, Agent Mike Smith provisionally elected to prosecute Invention II, with traverse (claims 27-40). In addition, Agent Mike Smith provisionally elected species 2(b) directed to erythropoietin/erythropoietin analogs (claim 38).

Applicant must affirm this election in Applicant's replying to this Office action.

Claims 1-26 and 41-64 are withdrawn from further consideration, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claims 34 and 37 are withdrawn from further consideration, 37 CFR 1.142(b), as being drawn to non-elected species.

Currently, claims 27-33, 35-36 and 38-40 are under examination.

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0063], the quoted term "recognizes" is indefinite. Whether/how the information contained therein departs or digresses from the plain meaning of the term "recognizes" is not clear.

In paragraph [0065]:

The second sentence reference to "[t]he specificity" appears repugnant to the general definition of "specifically binds" set forth in paragraph [0059].

The third sentence exclusion of "inhibition" and "adverse biological reaction" from the definition of "therapeutic inactivating component" appears repugnant to the general definition of "therapeutic inactivating component" as set forth in paragraph [0052].

In the fourth sentence, the object "a selection" is indefinite. The identity of one or more objects and/or steps required for "a selection" is not clear.

In the fifth sentence, the modifier "relevant" with respect to "therapeutic inactivating components" is indefinite. The identity of one or more objects and/or steps required for a "relevant" therapeutic inactivating components is not clear.

The third sentence expansion of the definition of "therapeutic inactivating component" to add entities "that affect the biological activity" appears repugnant to the general definition of "therapeutic inactivating component" as set forth in paragraph [0052].

Appropriate correction is required.

Claim Objections

Claims 32-33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, Examiner is unable to determine whether the recitations of "a health care provider" and "a health care management entity" in claim 32, and "clinical lab" in claim 33 materially alter the scope of parent claim 27.

Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-33, 35-36 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27:

Claim 27 appears incomplete and appears to omit essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Specifically, the preamble recites “[a] method for determining or monitoring a therapeutic protocol”, while final step d) recites the step of “deciding”. Whether/how the mere step of “deciding” amounts to “[a] method for determining or monitoring a therapeutic protocol” is not clear. The method steps related to “determining or monitoring a therapeutic protocol” appear omitted. .

The preamble passive voice phrase “said auto antibody developed” is indefinite. The identity of one or more object(s) and/or step(s), if any, required for performing “developing” is not clear.

The informational product of step b) does not appear to have any function in the overall method of claim 27. The purpose of step b) in the overall method is not clear.

In step c), the phrase “said auto antibody that specifically binds said natural substance” lacks antecedent basis.

Art Unit: 1641

In step d), the phrase "said assessed auto antibody" lacks antecedent basis.

In claim 32:

The object "the decision" lacks antecedent basis in claim 27.

The objects "a health care provider" and "a health care management entity" are indefinite.

Whether/how territorial jurisdiction or governmental political or judicial authority to practice medicine or form corporate entities affects the scope of Applicant's claim is not clear.

In claim 33, the term "clinical lab" is indefinite. The identity of one or more necessary and sufficient objects required for "clinical lab" is not clear.

In claim 35:

The term "the therapeutic agent" lacks antecedent basis in claim 27.

The pronoun "that" is indefinite. The identity of one or more objects referenced by "that" is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-28, 30-33, 35-36 and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Conti-Fine (US 6,759,385).

Conti-Fine describes a method for determining a therapeutic protocol for a subject afflicted with an auto antibody specific for a natural substance, wherein said auto antibody developed as a result of therapeutic administration of the natural substance (see e.g., col. 6, lines 61-63, "a method to inhibit or suppress an antibody-mediated disease that is associated with the administration of an endogenous protein"), the method comprising the steps of:

- a) obtaining a sample from said subject (see e.g., col. 5, line 67, "samples");
- b) assessing said sample for the presence of said natural substance (see e.g., col. 23, lines 30-31, "the antigen which is associated with the indication or disease is identified"; lines 35-36, "[t]he amino acid sequence of that antigen is then obtained or determined");

Art Unit: 1641

- c) assessing said sample for the presence of said auto antibody that specifically binds said natural substance (see e.g., col. 24, lines 21-23, "the amount of antibody specific for the antigen obtained at time periods before immunization and after immunization");
- d) deciding to initiate administration of the natural substance (see e.g., col. 7, lines 43-48, "the mammal is subjected to exogenous introduction of the protein... an amount of an epitope peptide... or a combination thereof") (paraphrasing mine).

With respect to claim 31, Conti-Fine describes a sandwich assay (see col. 24, line 7, "immunospot ELISA").

With respect to claims 39-40, Conti-Fine describes natural substances (see e.g., col. 23, lines 30-31, "the antigen which is associated with the indication or disease is identified"; lines 35-36, "[t]he amino acid sequence of that antigen is then obtained or determined") bound by a low molecular weight labels (see col. 23, line 10, "Fpitope").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conti-Fine (US 6,759,385) in view of Bunn, 346 N. ENGL. J. MED. 522 (2002).

Conti-Fine describes a method for determining a therapeutic protocol as substantially described, *supra*, and incorporated herein.

Conti-Fine does not teach a method incorporating "erythropoietin".

However, Bunn describes a method of deciding to initiate or terminate administration of "erythropoietin" (see p. 522, left column, third paragraph, first sentence, "[t]he article by Casadevall et al. in this issue of the Journal") based on an assessed autoantibody (see p. 522, left column, third paragraph, second sentence, "immune response to epoietin") against both endogenous erythropoietin and recombinant erythropoietin (see p. 522, right column, second paragraph, second sentence, "the antibody must react not only with epoietin but also with the small amount of endogenous erythropoietin").

It would have been obvious for a person of ordinary skill in the art to apply the method of determining a therapeutic protocol, as described by Conti-Fine, to erythropoietin because, according to Bunn, "about 3 million patients worldwide are being treated with epoietin" and because "[t]he clinical picture of rapidly

Art Unit: 1641

developing transfusion-dependent anemia is so dramatic that such cases are unlikely to escape attention"
(see paragraph bridging pp. 522-523).

Art Unit: 1641

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

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